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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,588	01/16/2001	Melton B. Affrime	AL01132K	4299

7590 03/08/2007

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washington, DC 20004-2401

EXAMINER
JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
2 MONTHS	03/08/2007	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/760,588
Filing Date: January 16, 2001
Appellant(s): AFFRIME ET AL.

Paul Berman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 3, 2006 appealing the Office action mailed June 16, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The judicial proceedings related to U.S. Patent Nos. 6,100,274 and 6,979,463 are noted on pages 5-6 of the appeal brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,100,274	Kou	8-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 69-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Kou U.S. Patent No. 6,100,274.

Kou discloses the invention substantially as claimed. Specifically, Kou discloses a method of treating allergic reactions in a mammal, the method comprising orally administering to the mammal, the method comprising orally administering to the mammal an anti-allergic effective amount of a pharmaceutical composition containing (preferred, 5-10 mg/day in a single or divided doses) descarbonylethoxyloratadine, i.e. desloratadine. The most preferred amount is 5 mg once a day. Kou discloses that desloratadine possesses antihistaminic properties. Please see the abstract; column 5, lines 43-56; claim 1.

The claims are anticipated by Kou because Kou discloses administration of a pharmaceutical composition containing an identical compound, i.e. desloratadine, at identical dosages, i.e. 5 mg/day, using appellant's claimed method steps. Accordingly, treatment of nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis as well as chronic idiopathic urticaria in a human of 12 years or older would be inherent. Moreover, in the absence of a definition of the term "about" as it pertains to the number of days of administration, the examiner respectfully submits that one of ordinary skill in the art is able to readily envisage about 10 days of treatment from the disclosure of Kou and is therefore anticipated. Concerning the claimed pharmacokinetic profile/blood and plasma concentrations, these are inherent within the dosages achieved and administered to mammals suffering from allergies, whether the symptoms of said allergies be "nasal" or "non-nasal" symptoms of seasonal and perennial allergic rhinitis or chronic idiopathic urticaria.

Additionally, it is reasonable to conclude that the same patient is being administered the same composition by the same mode of administration in the same amount in both the instant claims and the Kou reference. The fact that appellant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on the method. Furthermore, it does not appear that the claim language or limitation result in a manipulative difference in the method steps when compared to the prior art disclosure. Please see Bristol-Meyers Squibb Co. v. Ben Venue Laboratories, 58 USPQ2d 1508 (CAFC 2001).

(10) Response to Argument

In the arguments regarding In re Woodruff, it appears that the cite was misplaced. The cite for the discovery of yet another beneficial effect from the prior art should have been In re Best. The MPEP 2112 [R-3] at part I states that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Regarding appellants' argument that the examiner has ignored the steady state pharmacokinetic profile to be targeted by the administration of desloratadine, the use of the word "target" in all claims except claim 79 is noted. The word "target" in independent claims 69, 73, 76, 80 and 81 is interpreted as having goal that may or may not be achieved. Thus, the Kou '274 patent would anticipate these claims, wherein there is a dose of 5 to 10 mg per day administered in a single or divided dose, and the course of precise dosage and dosage regimen may be varied depending upon the requirements of the patients as well as the severity of the allergic condition being treated. Either way, a pharmacokinetic level of about 4 ng/ml would be "targeted", and since appellant has discovered subsequently that the C_{max} after about 10 days is about 4 ng/ml, that amount would be inherent in the administration of the same dosage

amount and same dosage regimen, as recommended by a physician as stated in Kou '274 (column 5, lines 43-54). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Appellant asserts that the examiner has applied an incorrect standard for inherent anticipation by relying on probabilities or possibilities as in the MPEP §2112 part IV. In response, the MPEP §2112[R3] part IV also states that "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original), which the examiner has done by pointing to the statement in Kou '274 that the desloratadine is administered in a dose of 5 to 10 mg per day administered in a single or divided dose, and the course of precise dosage and dosage regimen may be varied depending upon the requirements of the patients as well as the severity of the allergic condition being treated and the determination of a proper dosage and dosage regimen for a particular patient will be within the skill of the attending physician (column 5, lines 43-54). Whether it be it treatment of the common cold accompanied by rhinitis (usually about 10 days) or seasonal allergies accompanied by urticaria, a physician would make a determination for the length of treatment. Once a reference teaching a product appearing to be substantially identical is made the basis of a rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the appellant to

show an unobvious difference. The Appellant has failed to show an unobvious difference between the desloratadine of Kou and the desloratadine of the instantly claimed to "target" a C_{max} of 4 mg/ml.

Appellant states that the examiner did not answer arguments in the "response after final" rejection that the Kou patent does not discuss how to administer desloratadine in order to achieve an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/ml. In response, only claim 79 specifically states that a C_{max} of about 4 ng/ml is achieved. All other claims "target" the "about 4 ng/ml" range. It is the examiners position that Kou would "target" that range inherently by the administration of 5 to 10 mg/day in single or divided doses. The step of achieving about 4 ng/ml is absent in instant claims 69-78 and 80-84.

Appellant further charges that the examiner did not address arguments that the Kou patent does not discuss how to achieve an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose. It is the examiners position that unless there is a different base or tablet excipient, which is not recited in the instant claims, the time to maximum plasma concentration (T_{max}) would be inherent. An uneducated desloratadine tablet of the Kou patent being swallowed by a patient with rhinitis or seasonal allergies does not require an additional license to know that it will achieve a maximum plasma concentration within 3 hours of being swallowed. This knowledge would be inherent in the tablet, unless appellant is claiming some other tablet base that has a faster or slower dissolve/dissolution rate, of which there does not appear to be any. In response to Appellants argument that the

references fail to show certain features of appellant's invention, it is noted that the features upon which appellant relies (i.e., fasting state, or before or after eating resulting in a variable pharmacokinetic profile) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). There is no recitation in the instant claims whether the pharmacokinetic profile was achieved in a fasting state or not.

Regarding the limitation of 10 days as appellant argues in claims 73-75 and 82, that would be required to "target" the specified steady state desloratadine pharmacokinetic profile, the Kou patent teaches that "the course of precise dosage and dosage regimen may be varied depending upon the requirements of the patients as well as the severity of the allergic condition being treated and the determination of a proper dosage and dosage regimen for a particular patient will be within the skill of the attending physician" (column 5, lines 43-54). Whether it be it treatment of the common cold accompanied by rhinitis or seasonal allergies accompanied by urticaria, it is within the skill of the physician to make a determination for the length of treatment. Once a reference teaching a product appearing to be substantially identical is made the basis of a rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the appellant to show an unobvious difference. The Appellant has failed to show an unobvious difference between the desloratadine of Kou and the desloratadine of the instant application to "target" a C_{max} of about 4 ng/ml.

Further, in the ten days of treatment, achievement of the C_{max} of about 4 ng/ml is not required in claims 69-78 and 80-84. It is merely "targeted".

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Donna Jagoe

Conferees:

Ardin Marschel

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SUPERVISORY PATENT EXAMINER

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